

caBIG

Clinical Trials Management

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Adaptor: Data Provided

- Access to Breast SPORE Phase II clinical trial data: past accrual and real-time accrual
 - Data types: clinical, laboratory, radiology, tissue collection and imaging, genomic/ microarray
- Extended to other clinical trial activity:
 - Breast SPORE
 - Program Project Grant
 - Cancer Center Clinical Trials Shared Resource



Envisioned Tools

- Electronic administrative management tool
- Electronic data management tool
- Electronic data entry interface
- Web-based application
- Report writing tools
- Dataset output: SAS, S-Plus, Excel
- Site specific access for remote data collection site: web portals

Evaluation of Adopted Tools

- Systematic feedback mechanism:
 - Designated adoptor team:
 - Clinical workflow: principal investigator, clinical research assistants and other clinical staff
 - Data workflow: data entry, data manager and other database staff



System Integration

- Cancer Center Information Systems is committed to conform to established and chosen caBIG standards
- Ability to use most platforms

End User Testing

- Data Manager and Programmers will interact to provide
 - workflow testing
 - interface testing
 - data validity testing

Software validation

- Functional requirements and expectations will be determined and periodically examined during the course of implementation
- Assessment by data manager, programmers, statisticians and clinicians at the end of the pilot

Interaction with Workspace Developers

- Recognize that this is a cooperative venture
- Created a designated team towards the adoption of the clinical trials management tools
- Interact fully with the technical support available from the developers
- Attend quarterly meetings, conference calls and other information sessions

